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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,611	12/21/2001	Gerald Soslau	MCP-0056	4526

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EXAMINER	
GITOMER, RALPH J	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 05/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/029,611	SOSLAU, GERALD	
	Examiner	Art Unit	
	Ralph Gitomer	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 2* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

A reading of the specification does not reveal a singular point of novelty. What has been searched and considered here is screening for compounds that inhibit platelet activity by inhibiting GP Ib, PAR-1, or PAR-4. Regarding claim 2, alpha, beta, or gamma thrombin inhibiting has been searched. No novelty is seen.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 are rejected under 35 U.S.C. 102(a) as being anticipated by Schmaier.

Schmaier (6,544,750) entitled "Peptide Analogs as Selective Inhibitors of Thrombin Activation of Protease Activated Receptor 1" teaches in column 1 lines 30-36, PAR-1 is a specific substrate of thrombin and is expressed by platelets. In column 6 lines 31-61, compounds that inhibit alpha thrombin and gamma thrombin from activating platelets by cleaving PAR-1. In column 7 assays to screen libraries for platelet aggregation are shown. Gamma thrombin induced platelet aggregation was determined.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by each of Couglin, Hollenberg and South.

Coughlin (WO 99/43809) entitled "Protease Activated Receptor 4 and Uses Thereof" teaches in the abstract, screening candidate compounds for their ability to act as agonists or antagonists to the effects of interaction between thrombin and PAR 4. On page 19 Example 6, platelet aggregation assay is shown for PAR 4 function. On page 23 Example 10 is directed to platelets that express PAR-1 and 4.

Hollenberg (Bioactive Peptides in Drug Discovery and Design) entitled "Proteinase Activated Tethered Ligand Receptors" teaches on page 268 agonist assays for PAR 1 and 2 using a platelet aggregation assay. On page 269 peptide antagonists for PAR-1 in a platelet aggregation assay is shown.

South (Thrombosis and Haemostasis) entitled "Identification of Novel Peptide Antagonists for von Willebrand Factor Binding to the Platelet Glycoprotein 1b Receptor from a Phage Epitope Library" teaches in the abstract, inhibitors of the von Willebrand Factor platelet glycoprotein 1b interaction. On page 146 column 1 platelet binding assays are shown.

All the claimed features are taught by each of the above references for the same function as claimed.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xu.

Xu (6,436,400 B1) entitled "Protease Activated receptor PAR-4 ZCHEMR2" teaches in the abstract, PAR-4 is a target in drug screening. In column 1 members of G protein coupled receptor family include PAR-1, 2 and 3 which are expressed in platelets. Additional members of the PAR family are expected to exist. In column 6 PAR 1 and 4 are detected in human platelets. In column 22, uses of PAR-4 antagonists regarding the thrombin pathway is discussed. In column 23 last paragraph, cells expressing PAR-4 are used within screening assays.

The claims differ from Xu in that they recite platelet aggregation is the assay specified.

It would have been obvious to one of ordinary skill in this art at the time the invention was made to employ the method of Xu to screen for drugs to inhibit GP1b, PAR 1 or 4 binding in a platelet aggregation assay because Xu teaches peptide fragments which are derived from platelets and have the same function as the platelet receptors. The function of the derived fragments and platelets in the assays taught by Xu would be expected to be the same.

Regarding claim 2 directed to thrombin pathways, the relationship of PAR 4 and thrombin pathways is elucidated by Xu.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to screening for compounds but the specification shows no compounds that have the activities as claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in every occurrence.

In claim 1 line 2, platelet activity of what is not recited. In claim 1(b) "the ability" is improper because compounds have activities, not abilities. In claim 1 last line, "the compound" lacks antecedent basis.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

McComsey (6,365,617) teaches treating PAR-1 disorders.

Coughlin (5,892,014) entitled "DNA Encoding a Protease Activated Receptor 3" teaches PAR-3.

Rugeri (WO 93/16712) entitled "Mutant GP1balpha Fragments and Recombinant Expression Thereof" teaches GP1 receptor binding.

Andrade-Gordon (PNAS) teaches PAR activity assays.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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